REMARKS

Claims 2, 7, and 26-111 have been canceled. Upon entry of the present amendment, claims 1, 3-6, and 8-25, reading on SEQ ID NO: 1 (and its translation product, SEQ ID NO: 2), will be pending in the present application. Claims 4, 8, 10-12, 15, 16, 19-22 have been amended to delete matter related to non-elected inventions. Claims 8 and 10 also have been amended as further described below. Applicants reserve the right to prosecute all canceled or deleted subject matter in later filed patent applications. No new matter is believed to be added by the present amendment.

Objections

Claims 4, 8, 10 and 11 were objected to for reciting non-elected inventions (SEQ ID NO:3 and SEQ ID NO:4). These claims have been amended to delete references to SEQ ID NO:3 and SEQ ID NO:4. Accordingly, Applicants request that the objections be withdrawn.

35 USC § 101

Claims 1, 3-6 and 8-25 were rejected under 35 U.S.C. § 101 as allegedly lacking a specific and substantial asserted utility or a well-established utility. Applicants respectfully disagree with the rejection.

The Office Action states "...the specification does not disclose a function for SEQ ID NO: 1, or the encoded polypeptide of SEQ ID NO: 2, in the context of the cell or organism." (Office Action at page 3). Applicants respectfully disagree with this statement.

On the contrary, the specification provides a specific and substantial asserted utility for the claimed invention, as required by law. As stated in the MPEP:

> In most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101...[MPEP at 2107.02.III.A]

Applicants have complied with this requirement. For example, the specification states

> Inhibition of the activity of CatSper1 causes a substantial decrease in the motility of sperm cells....Therefore, inhibitors of the activity of the CatSper1 protein can prevent penetration of the ZP [zona pellucida] and can be used as male contraceptives in men or

> women to cause temporary, reversible infertility. (Specification at paragraph 57).

The specification teaches that SEQ ID NO:1 is a CatSper1 gene and that SEQ ID NO:1 encodes the CatSper1 protein of SEQ ID NO:2. Therefore, as indicated in the specification, and as would be readily understood by those of skill in the art, the claimed molecules and methods relating to CatSper1 have utility for, among other things, the identification and production of inhibitors of CatSper1 which can be used in contraception, and the identification and diagnosis of infertility problems relating to mutations in the CatSper1 gene, and the production of animal models of human male infertility. These are not "generic" utilities associated with any newly discovered gene or protein. On the contrary, they are specific, credible utilities that relate to the specific biological role of CatSper1 as discovered by the applicants and as embodied in the claimed inventions.

Therefore, Applicants respectfully request that the rejection under 35 U.S.C. 101 be reconsidered and withdrawn.

35 U.S.C. §112, First Paragraph

Claims 1, 3-6 and 8-25 were rejected for alleged lack of enablement "since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility…one skilled in the art clearly would not know how to use the claimed invention" and "for allegedly not teaching "how to use the claimed polynucleotides encoding the polypeptide of SEQ ID NO: 2 for any specific and substantial purpose. [For example, there is] no disclosure of particular disease states correlating to an alteration in levels or forms of the polypeptide such that the polynucleotide could be used as a diagnostic tool." (Office Action at page 7).

Applicants respectfully submit that this rejection should be reconsidered and withdrawn for the same reasons stated above with respect to the rejection under 35 U.S.C. 101. Specifically, Applicants submit that the application does, in fact, assert multiple specific and credible utilities for the claimed invention and that those of skill in the art would have no difficulty in using the claimed nucleic acids, kits, vectors and cells for the stated purposes.

For example, the CatSper1 protein is a clear target for the development of male contraceptives or diagnosis of male infertility. As explained in detail in the working examples

provided in the specification, CatSper1 knock-out mice were produced (Example 3) and demonstrated "dramatically reduced sperm motility" (Example 5) and the sperm were unable to fertilize eggs (Example 6).

Therefore, the CatSper1 nucleic acids have utility in producing animals models of human male fertility and infertility, in producing transformed cells expressing CatSper1 to screen for inhibitors of CatSper1 activity, for RNA expression profiling of human sperm to identify abnormalities of CatSper1 expression, for genetic testing of humans to identify mutations of CatSper1 responsible for infertility, and the like. Moreover, fragments of the complete coding sequence (*e.g.*, those encoding polypeptides likely to be antigenic; those encoding functional domains, and those likely to represent unique sequences in the genome) have clear utilities to those of skill in the art (*e.g.*, developing anti-Catsper1 antibodies, screening for ligands in affinity assays, isolating CatSper1 sequences from genomic or cDNA samples). These and other utilities are described at length in the specification.

Applicants respectfully submit that, given the substantial demonstration of CatSper1's critical role in sperm motility and fertility, the utility of the claimed invention is as clear as that for any pharmaceutical target, and that the patentability of pharmaceutical targets has been unquestioned for decades.

35 USC § 112, First Paragraph – Written Description

Claims 1, 3-6, 8, 10 and 11 were rejected under 35 U.S.C. 112, first paragraph, because the specification allegedly does not describe the specification in such a way as to reasonably convey to one skilled in the art that Applicants "had possession of the claimed invention."

Applicants respectfully disagree.

Claims 1, 3-6, 8, 10 and 11 are directed to CatSper1 nucleic acids, including subsequences of an entire CatSper1 nucleic acid, sequences encoding subsequences of an entire CatSper1 protein, sequences sharing at least 80% identity with a CatSper1 sequence, and sequences capable of hybridizing to a CatSper1 sequence under specified stringency conditions.

Applicants submit that they were clearly in possession of the complete CatSper1 nucleic acid and protein sequences. This much cannot be in doubt.

As such, Applicants submit that those of skill in the art would recognize that they were clearly in possession of subsequences as recited in claim 1. Indeed, it is difficult to understand

how one could be in possession of the entire sequence and yet not in possession of the subsequences.

Figure 1A clearly shows an entire CatSper1 sequence and delineates the positions of the transmembrane, loop and pore regions. The specification also provides a list of sequences having high predicted antigenicity. Therefore, Applicants submit that those of skill would clearly recognize that Applicants were in possession of the nucleic acids as recited in claims 3 and 4.

Given the complete CatSper1 nucleic acid sequence, one of skill in the art can clearly identify sequences which have 80% identity to that sequence, or any subsequence thereof. Therefore, Applicants submit that those of skill would clearly recognize that Applicants were in possession of the nucleic acids as recited in claim 5.

Given the complete CatSper1 nucleic acid sequence, and the experiments disclosed in the specification for detecting CatSper1 activity, one of skill in the art can clearly identify sequences which have 80% identity to that sequence and retain the activity. Therefore, Applicants submit that those of skill would clearly recognize that Applicants were in possession of the nucleic acids as recited in claim 6.

DNA hybridization experiments were well within the ability of those of skill in the art, at the time of filing. Given the complete CatSper1 nucleic acid sequence, and such routine skill, one of skill in the art can clearly identify sequences which hybridize under specified conditions. Therefore, Applicants submit that those of skill would clearly recognize that Applicants were in possession of the nucleic acids as recited in claim 8.

Finally, with respect to claims 10 and 11, which substantially include the limitations of claims 6 and 8 discussed above, one of skill in the art, particularly in view of the teachings of the specification, can clearly produce the claimed operably joined sequences. Therefore, Applicants submit that those of skill would clearly recognize that Applicants were in possession of the nucleic acids as recited in claims 10 and 11.

For the foregoing reasons, Applicants respectfully request that the rejections of claims 1, 3-6, 8, 10 and 11 under 35 U.S.C. 112, first paragraph, be reconsidered and withdrawn.

35 USC § 102

Claims 8, 10, and 12 were rejected under 35 U.S.C. 102(b) for alleged anticipation in view of Sanger Centre (1988, Science, 282:2012-2018, Accession No. Z82256.1). The Office Action states:

> The Sanger Centre Consortium discloses a polynucleotide sequence encoding a nematode sodium channel which is 29% identical to SEQ ID NO: 1 in the instant application. There are several short identical areas where the nucleotides are the same, such as in the region of residues 174-181. This reference meets the limitations of claims 8, 10, and 12 which cite "at least *a portion* of SEQ ID NO: 1," as well as hybridization steps that are not stringent (i.e., washing at 65C). (Office Action at page 11).

Claims 8 and 10 are amended herein to recite stringency conditions of 0.1 x SSC at 65°C. These conditions are not shown in the cited reference.

In view of the amendment, Applicants respectfully request that the rejection of Claims 8 and 10 under 35 U.S.C. 102 be reconsidered and withdrawn.

The Office Action suggests that there are "short identical" sequences between the cited reference and the claimed invention, and notes one sequence of 7 residues (174-181). Claim 12, however, is not anticipated by the cited reference because the nucleic acids which are the subject of claim 12 are not "short" sequences but, rather, range from sequences of at least 10 consecutive nucleotides which must be identical, to many hundreds of nucleotides encoding entire functional domains which require at least 80% identity.

Therefore, Applicants respectfully request that the rejection of claim 12 under 35 U.S.C. 102 be reconsidered and withdrawn.

CONCLUSION

Claims 2, 7, and 26-111 have been canceled. Claims 4, 8, 10-12, 15, 16, 19-22 have been amended. Upon entry of the present amendment, claims 1, 3-6, and 8-25 are pending in the present application. In view of the amendments and arguments made herein, Applicants respectfully request reconsideration of all claims, and submit that the claims are in condition for allowance.

This Amendment is being filed with a Petition for Extension of Time. No additional fees are believed to be due. However, if such a fee is due or a credit is owed, please make them to our Deposit Account No. 08-0219, referencing Attorney Docket No. 0110313.135US3.

Respectfully submitted,

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/Michael Twomey/
Michael Twomey
Registration No.: 38,349
Attorney for Applicant(s)

Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
(617) 526-6190 (telephone)
(617) 526-5000 (facsimile)